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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,181	04/09/2004	Kullervo Hyninen	18989-030 UTILA	1772
30623	7590	04/26/2006	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			JAWORSKI, FRANCIS J	
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/822,181	Applicant(s) HYNYNEN ET AL. c	
	Examiner Jaworski Francis J.	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/1, 11/30/04 IDS.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/1, 11/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 –8, 15, 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Perelgut (US2004/0019262) which teaches method and apparatus for adapting seismic techniques to imaging investigation of a tooth or bone, in the case of the jaw a skull bone, and including investigation of fluid canals and orifices using shear (S) as well as longitudinal pressure (P) wave information induced by the ensonating ultrasound plane or cylindrical wave (characterizable as a 'main beam' since no ghosting or sidelobe effects are described) applied along a 'line of profile' or linear region. The imaging process is intended to provide additional information with respect to anatomic dental images e.g. obtained by x-ray device.

Claims 1 – 5, 15 – 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Antich et al (US5,197,475) which teaches a method and apparatus for applying a beamed ultrasound wave (here 'main beam' is imputed to mean a focused or spatially directed energization) to bone at the critical longitudinal pressure (P) and shear (S) wave angles with analysis of the reflected and scattered ultrasound energy, and including production of a form of image per col. 8 lines 14 – 20, and including a

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positioner associated with each embodiment and configured to energize for example single elements in order to leave the mainbeam narrowly directed at the bone surface as the intercept angles are varied.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 8, 15 – 21, 28 are rejected under 35 U.S.C. 103(a) as being obvious over (a) Perelgut or (b) Sarvazyan et al (US5810731) alone or further in view of Trahey et al (US6764448), in any case further in view of Antich et al (US5197475).

Whereas Perelgut et al may be viewed as primarily a dental/orthodontic and not directed to skull imaging in the intracranial sense, Sarvazyan et al alone or in view of

Trahey et al are so directed (see Sarvazyan col. 3 lines 13 – 17 and cols. 5 – 6 bridging) and note that whereas in Sarvazyan et al the shear wave is generated by pulse amplitude modulation of the ultrasound focused beamed wave, in Trahey et al a virtual extended shear wave source is used without the low frequency variation by amplitude modulation in the former (see col. 1 lines 28 – 37) but is assumed to be sister technology i.e. an improvement patent wrt to the Sarvazyan shear wave brain scanner and therefore is grouped therewith for treatment of the variant/

Since whereas the former do not discuss ensonating with a beamed wave at an incident beam angle in relation to a longitudinal and transverse (shear) wave critical angle, it would have been obvious in view of the latter cols. 9 – 11 to used angle-controlled beaming via a positioner and selectively actuatable elements to relate these critical angles to component velocities which determine relative arrival times.

Claims 9 – 14 ,22 – 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antich et al or, (a) Perelgut or (b) Sarvazyan et al alone or further in view of Trahey et al , further in view of Antich et al as applied to claims above, and further in view of Hoff et al (US6899680), since whereas the former are silent as to use of pulses of varying duration and amplitude and frequency, the latter in cols. 11 – 17 teaches that P and/or S wave analysis may be conducted in the 3 – 10 Mhz range and with amplitude and frequency variations at least to assess concurrently the non-linearity features of the investigated tissues, arguments otherwise being as applied above.

Patentability Assessment

The rejection arguments may be clarified informally as follows: Ultrasound shear wave-based 'non-anatomic imaging' technology was heretofore present for purposes e.g. of osteoporosis assessment e.g. in long bones or heel or patella (Antich et al, Hoff et al, also Kantorovich et al infra not part of the arguments) where critical angle techniques were practiced. Ultrasound shear-wave-based anatomic imaging technology was heretofore present in relation to dentistry and local jaw bone assessment (Perelgut in the specialized context of a seismic adaptation and to a lesser extent Asch et al infra, not part of the arguments). Shear wave-based anatomic imaging of the brain through the skull as a core topic was known per Sarvazyan et al and Trahey et al as an improvement variant (albeit the latter does not mention bone or intracranial or skull usages). Since these are all interrelated in the fundamental S/P wave analysis or equivalent compression-longitudinal or transverse-shear language equivalents the Examiner has presented these in the most relevant reference combination arguments to assure their full consideration and elicit the exclusivity distinctions and claims' wordings that represent the applicants' invention, which distinctions and wordings are elusive to the Examiner at this juncture.

Fink et al (US6770033) and Bonnefous (US6561981) are directed to shear wave ultrasound imaging where the shear waves are not ultrasound-induced but are delivered by an external low frequency vibratory source 2. and the imaging is of dynamic viscosity of a viscoelastic tissue region in the former and of tissue and shear wave front velocity in the latter.

Winder (US6585647) is directed to using radar/sonar-derived Synthetic Structural Imaging ramp response to generate ultrasound vibrational shear modes, col. 9 line 27 – col. 10 line 29, with oblique reference to targeting of bone, col. 7 lines 52 – 55.

Naville (US4789969) is directed to measurement of shear wave anisotropy inter alia in medical applications, col. 1 lines 32 – 35.

Kubota et al (US3996792) is directed to longitudinal and shear wave flaw detection based upon scan incident angle in environments alternative to medical imaging, per col. 1-2 discussion.

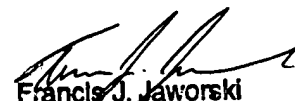
Asch et al (US6638219) mentions briefly that a shear wave response may be processed in a three-dimensional ultrasound dental imager in order to pinpoint an internal reflective echo source.

Kantorovich et al (US5426979) is directed inter alia to bone analysis using shear waves 44 (termed transverse waves therein.).

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

042406



Francis J. Jaworski
Primary Examiner